

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

Form 8-K

Current Report  
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 7, 2024

AXOGEN, INC.

(Exact Name of Registrant as Specified in Charter)

Minnesota  
(State or Other Jurisdiction of  
Incorporation or Organization)

001-36046  
(Commission File Number)

41-1301878  
(I.R.S. Employer Identification No.)

13631 Progress Boulevard, Suite 400 Alachua, Florida  
(Address of principal executive offices)

32615  
(Zip Code)

(386) 462-6800  
(Registrant's telephone number, including area code)

N/A  
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)  
 Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)  
 Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))  
 Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, \$0.01 par value	AXGN	The Nasdaq Stock Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

## Item 2.02 Results of Operations and Financial Condition

On November 7, 2024 Axogen, Inc. (the “Company”) issued a press release announcing its third quarter of 2024 financial results. A copy of the press release is furnished as Exhibit 99.1.

The information furnished pursuant to Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1 hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of such section, nor shall it be incorporated by reference into future filings by the Company under the Securities Act of 1933, as amended (the “Securities Act”), or under the Exchange Act, unless the Company expressly sets forth in such future filing that such information is to be considered “filed” or incorporated by reference therein.

## Item 7.01 Regulation FD Disclosure

On November 7, 2024, the Company also posted an updated corporate presentation to its website at <https://ir.axogeninc.com/news-events>. The Company may use the investor presentation from time to time in conversation with analysts, investors, and others. A copy of the investor update is furnished as Exhibit 99.2.

The information in this Item 7.01 including Exhibit 99.2 is being furnished and shall not be deemed to be “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section and shall not be deemed incorporated by reference into any filing under the Securities Act or Exchange Act, except as shall be expressly set forth by specific reference in such filing.

## Item 9.01. Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Axogen Inc. Press Release, dated November 7, 2024</a>
99.2	<a href="#">Axogen, Inc. Corporate Presentation, dated November 7, 2024</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**SIGNATURES**

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AXOGEN, INC.

Dated: November 7, 2024

By: /s/ Marc Began

Marc Began

Executive Vice President, General Counsel and Chief Compliance Officer



## **Axogen, Inc Reports Third Quarter 2024 Financial Results and Provides BLA Update**

**ALACHUA and TAMPA, FL** – November 7, 2024 – Axogen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for peripheral nerve injuries, today reported financial results and business highlights for the third quarter ended September 30, 2024.

### **Third Quarter Financial Results**

- Third quarter revenue was \$48.6 million, a 17.9% increase compared to the third quarter of 2023.
- In the third quarter of 2024, gross margin decreased to 74.9%, down from 76.8% in the third quarter of 2023.
- Net loss for the quarter was \$1.9 million, or \$0.04 per share, compared to net loss of \$4.1 million, or \$0.10 per share in the third quarter of 2023.
- Adjusted net income for the quarter was \$3.1 million, or \$0.07 per share, compared to adjusted net loss of \$0.7 million, or \$0.01 per share, in the third quarter of 2023.
- Adjusted EBITDA was \$6.5 million for the quarter, compared to an adjusted EBITDA of \$2.4 million in the third quarter of 2023.
- The balance of all cash, cash equivalents, and investments on September 30, 2024, was \$30.5 million, as compared to a balance of \$27.1 million on June 30, 2024

“We are pleased with the third quarter’s topline revenue and EBITDA growth. Notably, our revenue performance in the quarter was broad based across our entire portfolio of nerve repair and protection applications, reflecting improved sales productivity and commercial execution,” commented Michael Dale, CEO and Director of Axogen, Inc. “Since joining the Axogen team, everything I’ve observed and experienced reaffirms my estimation that we have significant undeveloped potential to make nerve repair an expected standard of care around the world.”

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## Summary of Business Highlights

- On November 1<sup>st</sup>, the U.S. Food and Drug Administration (FDA) notified the company that they accepted the filing of its Biologics License Application (BLA) for Avance Nerve Graft<sup>®</sup> under a standard review and assigned a Prescription Drug User Fee Act (PDUFA) goal date of September 5<sup>th</sup>, 2025. The FDA further indicated that it does not currently plan to hold an advisory committee for the application.
- During the quarter, at the American Society for Surgery of the Hand (ASSH), we presented novel data highlighting the extent of nerve damage that occurs in common injuries, the importance of protection of the nerve coaptation site and the growing role of Avance Nerve Graft in sensory, mixed and motor nerve repair.
- Recently, we executed on a National Resensation Breast program as well as numerous regional surgeon education programs in Extremities and Head & Neck.

## 2024 Financial Guidance

We are maintaining our full year revenue guidance in the range of \$182 million to \$186 million, and now expect to be at the high end of our 74-76% full year gross margin range. Additionally, we reiterate that we expect to be net cash flow positive cumulatively for the period from April 1st through year end.

## Conference Call

The Company will host a conference call and webcast for the investment community today at 8:00 a.m. ET. Investors interested in participating in the conference call by phone may do so by dialing toll free at (877) 407-0993 or use the direct dial-in number at (201) 689-8795. Those interested in listening to the conference call live via the Internet may do so by visiting the Investors page of the Company's website at [www.axogeninc.com](http://www.axogeninc.com) and clicking on the webcast link.

Following the conference call, a replay will be available in the Investors section of the Company's website at [www.axogeninc.com](http://www.axogeninc.com) under Investors.

## About Axogen

Axogen (AXGN) is the leading Company focused specifically on the science, development, and commercialization of technologies for peripheral nerve regeneration and repair. Axogen employees are passionate about helping to restore peripheral nerve function and quality of life to patients with physical damage or transection to peripheral nerves by providing innovative, clinically proven, and economically effective repair solutions for surgeons and health care providers. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body. Every day, people suffer traumatic injuries or undergo surgical procedures that impact the function of their peripheral nerves. Physical damage to a peripheral nerve, or the inability to properly reconnect peripheral nerves, can result in the loss of muscle or organ function, the loss of sensory feeling, or the initiation of pain.

Axogen's platform for peripheral nerve repair features a comprehensive portfolio of products used across various applications and surgical specialties, including traumatic injuries, oral and maxillofacial surgery, breast reconstruction, and the surgical treatment of pain. These applications encompass both scheduled and emergent procedures. Specifically, scheduled procedures are often pursued by patients seeking relief from conditions caused by a nerve defect or previous surgical interventions. Such

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procedures include providing sensation for women undergoing breast reconstruction following a mastectomy, nerve reconstruction after the surgical removal of painful neuromas, and oral and maxillofacial procedures, as well as nerve decompression. Conversely, emergent procedures typically arise from injuries that initially present in an emergency room, with specialists intervening either immediately or within a few days following the initial injury. This broad range of applications underscores Axogen's vital role in addressing diverse patient needs in peripheral nerve repair.

Axogen's platform for peripheral nerve repair features a comprehensive portfolio of products, including Avance® Nerve Graft, a biologically active off-the-shelf processed human nerve allograft for bridging severed peripheral nerves without the comorbidities associated with a second surgical site; Axoguard Nerve Connector®, a porcine submucosa extracellular matrix (ECM) coaptation aid for tensionless repair of severed peripheral nerves; Axoguard Nerve Protector®, a porcine submucosa ECM product used to wrap and protect damaged peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments; Axoguard HA+ Nerve Protector™, a porcine submucosa ECM base layer coated with a proprietary hyaluronate-alginate gel, a next-generation technology designed to enhance nerve gliding and provide short- and long-term protection for peripheral nerve injuries; Avive+ Soft Tissue Matrix™, a multi-layer amniotic membrane allograft used to protect and separate tissues in the surgical bed during the critical phase of tissue repair; and Axoguard Nerve Cap®, a porcine submucosa ECM product used to protect a peripheral nerve end and separate the nerve from the surrounding environment to reduce the development of symptomatic or painful neuroma. The Axogen portfolio of products is available in the United States, Canada, the United Kingdom, South Korea, and several other European and international countries.

For more information, visit [www.axogeninc.com](http://www.axogeninc.com).

### **Cautionary Statements Concerning Forward-Looking Statements**

This press release contains "forward-looking" statements as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations or predictions of future conditions, events, or results based on various assumptions and management's estimates of trends and economic factors in the markets in which we are active, as well as our business plans. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates," "projects," "forecasts," "continue," "may," "should," "will," "goals," and variations of such words and similar expressions are intended to identify such forward-looking statements. Forward-looking statements include, without limitation, the estimation of significant undeveloped potential to make nerve repair an expected standard of care around the world, the Company's expectations regarding the potential for approval of the BLA in September 2025, as well as statements under the subheading "2024 Financial Guidance." Actual results or events could differ materially from those described in any forward-looking statements as a result of various factors, including, without limitation, global supply chain issues, hospital staffing issues, product development, product potential, clinical outcomes, regulatory process and approvals, financial performance, sales growth, surgeon and product adoption, market awareness of our products, data validation, our visibility at and sponsorship of conferences and educational events, global business disruption caused by Russia's invasion of Ukraine and related sanctions, recent geopolitical conflicts in the Middle East, potential disruptions due to management transitions, as well as those risk factors described under Part I, Item 1A, "Risk Factors," of our Annual Report on Form 10-K for the most recently ended fiscal year and in our subsequent Quarterly Reports on Form 10Q. Forward-looking statements are not a guarantee of future performance, and actual results may differ materially from those projected. The forward-looking statements are representative only as of the date

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they are made and, except as required by applicable law, we assume no responsibility to publicly update or revise any forward-looking statements.

### **About Non-GAAP Financial Measures**

To supplement our condensed consolidated financial statements, we use the non-GAAP financial measures of EBITDA, which measures earnings before interest, income taxes, depreciation and amortization, and Adjusted EBITDA which further excludes non-cash stock compensation expense and litigation and related expenses. We also use the non-GAAP financial measures of Adjusted Net Income or Loss and Adjusted Net Income or Loss Per Common Share - basic and diluted which excludes non-cash stock compensation expense and litigation and related expenses from Net Loss and Net Loss Per Common Share - basic and diluted, respectively. These non-GAAP measures are not based on any comprehensive set of accounting rules or principles and should not be considered a substitute for, or superior to, financial measures calculated in accordance with GAAP, and may be different from non-GAAP measures used by other companies. In addition, these non-GAAP measures should be read in conjunction with our financial statements prepared in accordance with GAAP. The reconciliations of the non-GAAP measures to the most directly comparable financial measures calculated and presented in accordance with GAAP should be carefully evaluated.

We use these non-GAAP financial measures for financial and operational decision-making and as a means to evaluate period-to-period comparisons. We believe that these non-GAAP financial measures provide meaningful supplemental information regarding our performance and that both management and investors benefit from referring to these non-GAAP financial measures in assessing our performance and when planning, forecasting, and analyzing future periods. We believe these non-GAAP financial measures are useful to investors because (1) they allow for greater transparency with respect to key metrics used by management in its financial and operational decision-making and (2) they are used by our institutional investors and the analyst community to help them analyze the performance of our business, the Company's cash available for operations, and the Company's ability to meet future capital expenditure and working capital requirements.

Contact:  
Axogen, Inc.  
[InvestorRelations@axogeninc.com](mailto:InvestorRelations@axogeninc.com)

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**AXOGEN, INC.**  
**Condensed Consolidated Balance Sheets**  
**(unaudited)**  
**(In thousands, except share and per share amounts)**

	September 30, 2024	December 31, 2023
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 18,662	\$ 31,024
Restricted cash	6,000	6,002
Investments	5,868	—
Accounts receivable, net of allowance for doubtful accounts of \$888 and \$337, respectively	24,629	25,147
Inventory, net	29,363	23,020
Prepaid expenses and other	1,730	2,811
<b>Total current assets</b>	<b>86,252</b>	<b>88,004</b>
Property and equipment, net	85,632	88,730
Operating lease right-of-use assets	14,886	15,562
Intangible assets, net	5,215	4,531
<b>Total assets</b>	<b>\$ 191,985</b>	<b>\$ 196,827</b>
<b>Liabilities and shareholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 21,177	\$ 28,883
Current maturities of long-term lease obligations	1,856	1,547
<b>Total current liabilities</b>	<b>23,033</b>	<b>30,430</b>
Long-term debt, net of debt discount and financing fees	47,272	46,603
Long-term lease obligations	19,734	21,142
Debt derivative liabilities	2,445	2,987
Other long-term liabilities	94	—
<b>Total liabilities</b>	<b>92,578</b>	<b>101,162</b>
<b>Commitments and contingencies - see Note 12</b>		
<b>Shareholders' equity:</b>		
Common stock, \$0.01 par value per share; 100,000,000 shares authorized; 44,002,323 and 43,124,496 shares issued and outstanding	440	431
Additional paid-in capital	390,677	376,530
Accumulated deficit	(291,710)	(281,296)
<b>Total shareholders' equity</b>	<b>99,407</b>	<b>95,665</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 191,985</b>	<b>\$ 196,827</b>



**AXOGEN, INC.**  
**Condensed Consolidated Statements of Operations**  
**(unaudited)**  
**(In thousands, Except share and per share amounts)**

	Three Months Ended		Nine Months Ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
<b>Revenues</b>	\$ 48,644	\$ 41,271	\$ 137,933	\$ 116,090
<b>Cost of goods sold</b>	12,206	9,567	33,531	26,242
<b>Gross profit</b>	36,438	31,704	104,402	89,848
<b>Costs and expenses:</b>				
Sales and marketing	18,924	19,165	58,437	57,471
Research and development	6,996	6,694	21,063	20,164
General and administrative	10,834	9,870	30,206	30,481
<b>Total costs and expenses</b>	36,754	35,729	109,706	108,116
<b>Loss from operations</b>	(316)	(4,025)	(5,304)	(18,268)
<b>Other income (expense):</b>				
Investment income	296	367	816	1,151
Rental income	90	—	90	—
Interest expense	(1,893)	(827)	(6,405)	(992)
Change in fair value of derivatives	13	402	542	649
Other expense	(48)	(6)	(153)	(363)
<b>Total other (expense) income, net</b>	(1,542)	(64)	(5,110)	445
<b>Net loss</b>	\$ (1,858)	\$ (4,089)	\$ (10,414)	\$ (17,823)
Weighted average common shares outstanding — basic and diluted	43,882,110	43,022,328	43,610,481	42,821,284
Loss per common share — basic and diluted	\$ (0.04)	\$ (0.10)	\$ (0.24)	\$ (0.42)

**AXOGEN INC.**  
**RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES**  
**(unaudited)**  
**(In thousands, except per share amounts)**

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30, 2024</b>	<b>September 30, 2023</b>	<b>September 30, 2024</b>	<b>September 30, 2023</b>
<b>Net loss</b>	\$ (1,858)	\$ (4,089)	\$ (10,414)	\$ (17,823)
Depreciation and amortization expense	1,719	1,224	5,034	2,874
Investment income	(296)	(367)	(816)	(1,151)
Income tax expense	26	12	76	331
Interest expense	1,893	827	6,405	992
<b>EBITDA - non GAAP</b>	<b>\$ 1,484</b>	<b>\$ (2,393)</b>	<b>\$ 285</b>	<b>\$ (14,777)</b>
Non cash stock-based compensation expense	5,004	4,747	12,830	13,091
<b>Adjusted EBITDA - non GAAP</b>	<b>\$ 6,488</b>	<b>\$ 2,354</b>	<b>\$ 13,115</b>	<b>\$ (1,686)</b>
<b>Net loss</b>	<b>\$ (1,858)</b>	<b>\$ (4,089)</b>	<b>\$ (10,414)</b>	<b>\$ (17,823)</b>
Non cash stock-based compensation expense	5,004	4,747	12,830	13,091
<b>Adjusted net income (loss) - non GAAP</b>	<b>\$ 3,146</b>	<b>\$ 658</b>	<b>\$ 2,416</b>	<b>\$ (4,732)</b>
<b>Weighted average common shares outstanding basic and diluted</b>	<b>43,882,110</b>	<b>43,022,328</b>	<b>43,610,481</b>	<b>42,821,284</b>
<b>Loss per common share — basic and diluted</b>	<b>\$ (0.04)</b>	<b>\$ (0.10)</b>	<b>\$ (0.24)</b>	<b>\$ (0.42)</b>
Non cash stock-based compensation expense	0.11	0.11	0.29	0.31
<b>Adjusted net income (loss) per common share - basis and diluted - non GAAP</b>	<b>\$ 0.07</b>	<b>\$ 0.01</b>	<b>\$ 0.05</b>	<b>\$ (0.11)</b>

**AXOGEN, INC.**  
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**  
(unaudited)  
(In thousands, except per share)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount			
<b>Three Months Ended September 30, 2024</b>					
<b>Balance at June 30, 2024</b>	43,824,738	\$ 438	\$ 385,101	\$ (289,852)	\$ 95,687
Net loss	—	—	—	(1,858)	(1,858)
Stock-based compensation	—	—	5,004	—	5,004
Issuance of restricted and performance stock units	112,185	1	(1)	—	—
Exercise of stock options and employee stock purchase plan	65,400	1	573	—	574
<b>Balance at September 30, 2024</b>	<u>44,002,323</u>	<u>\$ 440</u>	<u>\$ 390,677</u>	<u>\$ (291,710)</u>	<u>\$ 99,407</u>
<b>Nine Months Ended September 30, 2024</b>					
<b>Balance at December 31, 2023</b>	43,124,496	\$ 431	\$ 376,530	\$ (281,296)	\$ 95,665,197
Net loss	—	—	—	(10,414)	(10,414)
Stock-based compensation	—	—	12,830	—	12,830
Issuance of restricted and performance stock units	695,571	7	(7)	—	—
Exercise of stock options and employee stock purchase plan	182,256	2	1,324	—	1,326
<b>Balance at September 30, 2024</b>	<u>44,002,323</u>	<u>\$ 440</u>	<u>\$ 390,677</u>	<u>\$ (291,710)</u>	<u>\$ 99,407</u>
<b>Three Months Ended September 30, 2023</b>					
<b>Balance at June 30, 2023</b>	42,979,541	\$ 430	\$ 370,036	\$ (273,314)	\$ 97,152
Net loss	—	—	—	(4,089)	(4,089)
Stock-based compensation	—	—	4,747	—	4,747
Issuance of restricted and performance stock units	59,858	—	—	—	—
Exercise of stock options and employee stock purchase plan	—	—	—	—	—
<b>Balance at September 30, 2023</b>	<u>43,039,399</u>	<u>\$ 430</u>	<u>\$ 374,783</u>	<u>\$ (277,403)</u>	<u>\$ 97,810</u>
<b>Nine Months Ended September 30, 2023</b>					
<b>Balance at December 31, 2022</b>	42,445,517	\$ 424	\$ 360,155	\$ (259,580)	\$ 100,999
Net loss	—	—	—	(17,823)	(17,823)
Stock-based compensation	—	—	13,091	—	13,091
Issuance of restricted and performance stock units	356,236	4	(4)	—	—
Exercise of stock options and employee stock purchase plan	237,646	2	1,541	—	1,543
<b>Balance at September 30, 2023</b>	<u>43,039,399</u>	<u>\$ 430</u>	<u>\$ 374,783</u>	<u>\$ (277,403)</u>	<u>\$ 97,810</u>

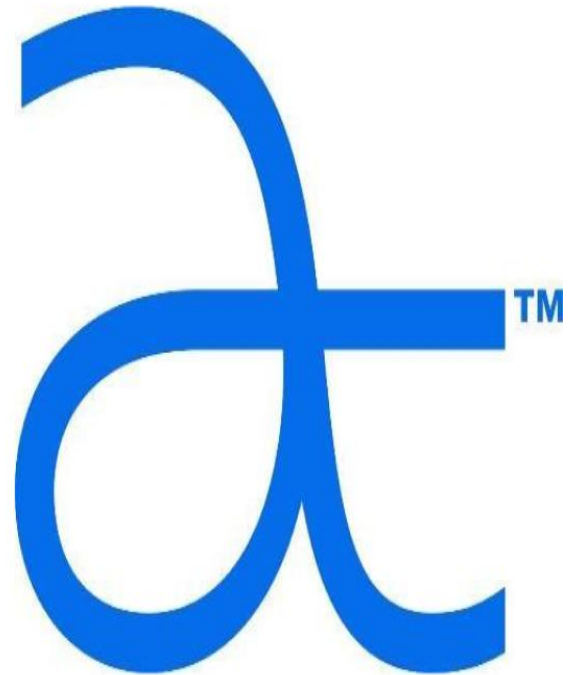
**AXOGEN, INC.**  
**Condensed Consolidated Statements of Cash Flows**  
**(unaudited)**

	Nine Months Ended	
	September 30, 2024	September 30, 2023
<b>Cash flows from operating activities:</b>		
Net loss	\$ (10,414)	\$ (17,823)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	4,831	2,660
Amortization of right-of-use assets	889	826
Amortization of intangible assets	202	214
Amortization of debt discount and deferred financing fees	669	666
Provision for (recovery of) bad debt	604	(311)
Change in fair value of derivatives	(542)	(649)
Investment (gains) loss	(95)	(660)
Share-based compensation	12,830	13,091
Change in operating assets and liabilities:		
Accounts receivable	(85)	(766)
Inventory	(6,343)	(4,114)
Prepaid expenses and other	1,189	(623)
Accounts payable and accrued expenses	(7,125)	3,012
Operating lease obligations	(1,303)	(1,012)
Cash paid for interest portion of finance leases	(2)	(2)
Other liabilities	495	(14)
<b>Net cash used in operating activities</b>	<b>\$ (4,200)</b>	<b>\$ (5,505)</b>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	\$ (2,431)	\$ (12,409)
Purchase of investments	(5,773)	(10,203)
Proceeds from sale of investments	—	42,874
Cash payments for intangible assets	(1,280)	(732)
<b>Net cash (used in) provided by investing activities</b>	<b>\$ (9,484)</b>	<b>\$ 19,530</b>
<b>Cash flows from financing activities:</b>		
Cash paid for debt portion of finance leases	\$ (6)	\$ (7)
Proceeds from exercise of stock options and ESPP stock purchases	1,326	1,543
<b>Net cash provided by financing activities</b>	<b>\$ 1,320</b>	<b>\$ 1,536</b>
<b>Net (decrease) increase in cash, cash equivalents, and restricted cash</b>	<b>(12,364)</b>	<b>15,561</b>
<b>Cash, cash equivalents, and restricted cash, beginning of period</b>	<b>37,026</b>	<b>21,535</b>
<b>Cash, cash equivalents, and restricted cash, end of period</b>	<b>\$ 24,662</b>	<b>\$ 37,096</b>

# Corporate presentation

November 7, 2024

nasdaq: axgn



**axogen<sup>®</sup>**

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# Safe harbor statement

This presentation contains “forward-looking” statements as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management’s current expectations or predictions of future conditions, events, or results based on various assumptions and management’s estimates of trends and economic factors in the markets in which we are active, as well as our business plans. Words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “seeks,” “estimates,” “projects,” “forecasts,” “continue,” “may,” “should,” “will,” “goals,” and variations of such words and similar expressions are intended to identify such forward-looking statements. Forward-looking statements include (1) the TAM for the targeted nerve markets, (2) 2024 financial guidance, including revenue range and gross margins, (3) growth drivers for the business, (4) expectations regarding the commercial performance of Avive+ Soft Tissue Matrix™, (5) the expectation that the Axogen Processing Center will support our BLA filing, (6) our expectations regarding our potential for BLA approval in September 2025, (7) the expectation that a new (non-biosimilar) competitive processed nerve allograft would need to complete clinical testing and obtain BLA approval prior to clinical release, and that it would likely take 8 years to achieve this, (8) the expectation that Avance® would be designated as the reference product for any biosimilar nerve allograft product and the expectation that approval of such a biosimilar would not occur for at least 12 years from approval of our BLA, and (9) the expectation that RECON<sup>SM</sup> study topline results will support our BLA filing.

Actual results or events could differ materially from those described in any forward-looking statements as a result of various factors, including, without limitation, statements related to potential disruptions caused by leadership transitions, global supply chain issues, record inflation, hospital staffing issues, product development, product potential, expected clinical enrollment timing and outcomes, regulatory process and approvals, financial performance, sales growth, surgeon and product adoption, market awareness of our products, data validation, our visibility at and sponsorship of conferences and educational events, global business disruption caused by Russia’s invasion of Ukraine and related sanctions, recent geopolitical conflicts in the Middle East, potential disruptions due to management transitions, as well as those risk factors described under Part I, Item 1A., “Risk Factors,” of our Annual Report on Form 10-K for the most recently ended fiscal year. Forward-looking statements are not a guarantee of future performance, and actual results may differ materially from those projected. The forward-looking statements are representative only as of the date they are made and, except as required by applicable law, we assume no responsibility to publicly update or revise any forward-looking statements.



# The Axogen platform for nerve repair

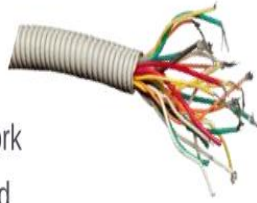


- Exclusively focused on peripheral nerve repair with a differentiated platform
- 15+ years of demonstrated clinical outcome consistency
- 275 peer-reviewed clinical publications
- Over 100,000 Avance® nerve grafts implanted
- Significant barriers to competitive entry
- Patient activation and surgeon education capabilities

# The function of nerves and injury types

Nerves are like wires

- Transfer signals across a network
- If cut, data cannot be transferred
- If crushed, short circuits and data corruption may occur



The peripheral nervous system is a vast network from every organ to and from the brain

- Sensory
- Motor
- Mixed








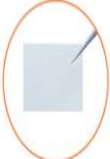





Nerves can be injured in three ways:

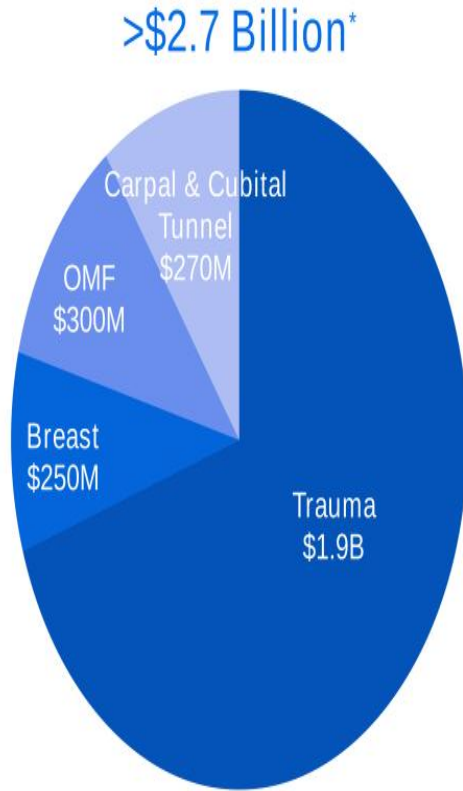
1. **Transection**  
Traumatic nerve injuries e.g., motor vehicle accidents, power tool accidents, battlefield injuries, gunshot wounds, surgical injuries, neuroma-in-continuity
2. **Compression**  
Carpal, cubital, tarsal tunnel revisions, blunt trauma, previous surgeries
3. **Stump Neuroma**  
Amputations, mastectomies, previous surgeries



# Comprehensive platform for addressing nerve injuries

 <b>avance</b> nerve graft	 <b>axoguard</b> nerve connector	 <b>axoguard HA+</b> nerve protector	 <b>axoguard</b> nerve protector	 <b>avive</b> soft tissue matrix	 <b>axoguard</b> nerve cap
					
Biologically active, processed human nerve allograft developed for bridging nerve discontinuities up to 70 mm	Semi-translucent coaptation aid for nerve transections up to 5 mm	Extracellular matrix base layer with a hyaluronate-alginate gel coating to facilitate enhanced nerve gliding, aid in minimizing soft tissue attachments and remodeling of the base layer to provide long-term protection	Extracellular matrix that remodels to protect injured nerves and reinforce nerve reconstructions	Multi-layer amniotic soft tissue barrier for protection during the critical stage of healing	Separates nerve end from surrounding environment to protect from mechanical stimulation and reduce painful neuroma formation
Connection		Protection		Termination	

# Targeted nerve markets (U.S.)



U.S. potential procedural estimates  
>900,000\*\*

- Trauma<sup>1-4</sup>: > 700,000
- Carpal and Cubital Tunnel Revisions<sup>5-8</sup>: 130,000
- Oral Maxillofacial (OMF)<sup>9-17</sup>: 56,000
- Breast Neurotization Procedures<sup>18</sup>: 15,000\*\*\*

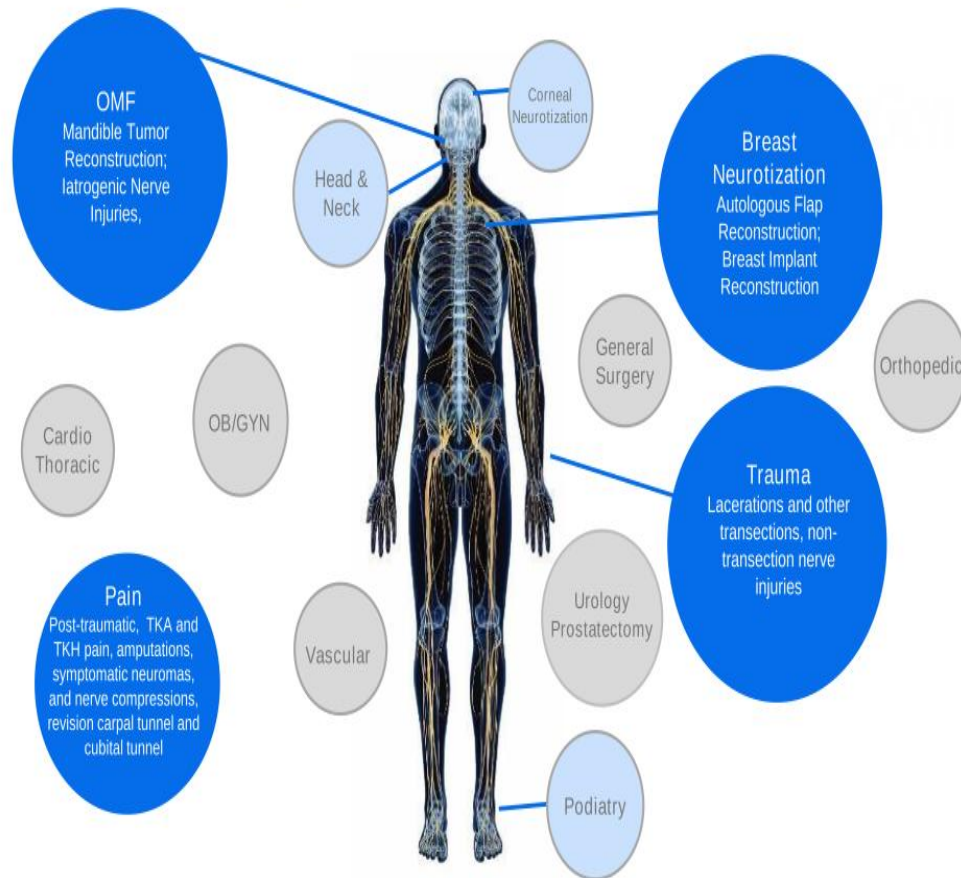
\*\$2.7B estimate does not include pain market or implant breast reconstruction neurotization

\*\*Referenced papers were used to derive specific assumptions in the procedure potential estimates. Papers used include both U.S. and OUS databases and studies. See Appendix for data sources.

\*\*\* Does not include implant-based procedures

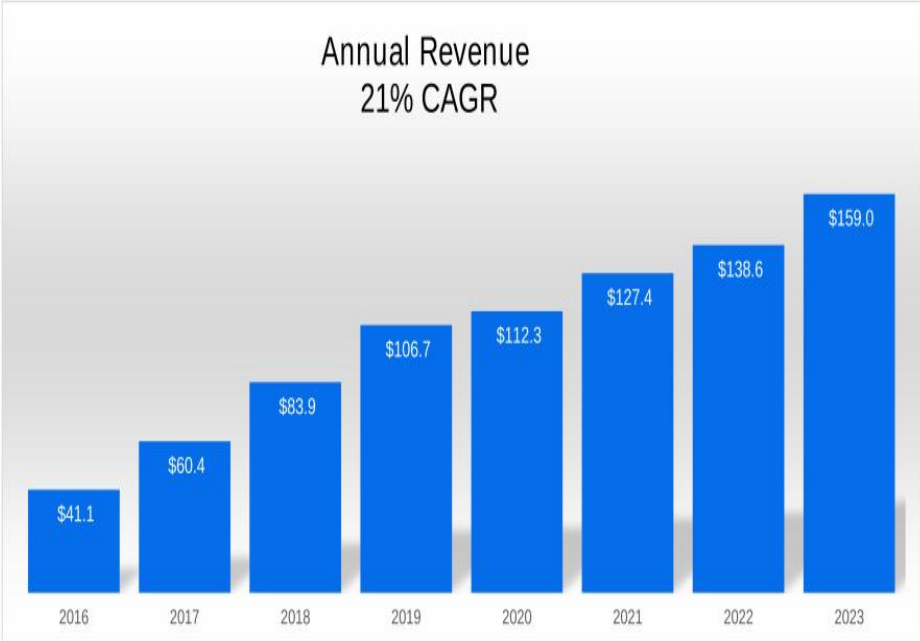
# Opportunities in nerve repair

Core business anchored in Trauma and Upper Extremity, and expanded to Breast, OMF and Pain. Further Market Expansion Opportunities in Head & Neck, Corneal Neurotization and Podiatry.



# Delivering strong revenue growth and gross margins

U.S. \$ in millions



## Management expects:

- Full-year 2024 revenue to be in the range of \$182 million to \$186 million.
- Additionally, we anticipate gross margin for the full year to be at the high end of the range of 74%-76%.
- We expect to be net cashflow positive cumulatively in the period from April 1st through year end.

74.9% gross margin for the quarter ended September 30, 2024



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# Growth drivers

## Clinical Data

- Clinical data published supports increased adoption particularly with middle adopters
  - RECON<sup>SM</sup> 19
  - Meta Analysis of clinical outcomes and Medicare Economic Data<sup>20</sup>
  - Premier Economic Data<sup>21</sup>
  - Cost-effectiveness analysis of Avance<sup>22</sup>

## Innovation

- New product launches in nerve protection: Axoguard HA+ Nerve Protector<sup>TM</sup> launched in Q2 2023, Avive+ Soft Tissue Matrix<sup>TM</sup> launched in Q2 2024
- Resensation<sup>®</sup> for breast neurotization expansion into implant-based reconstructions

Sales Rep Productivity driving penetration in high-potential accounts

Patient Activation Programs for breast neurotization, surgical treatment of pain, and OMF

Surgeon Education across nerve repair applications



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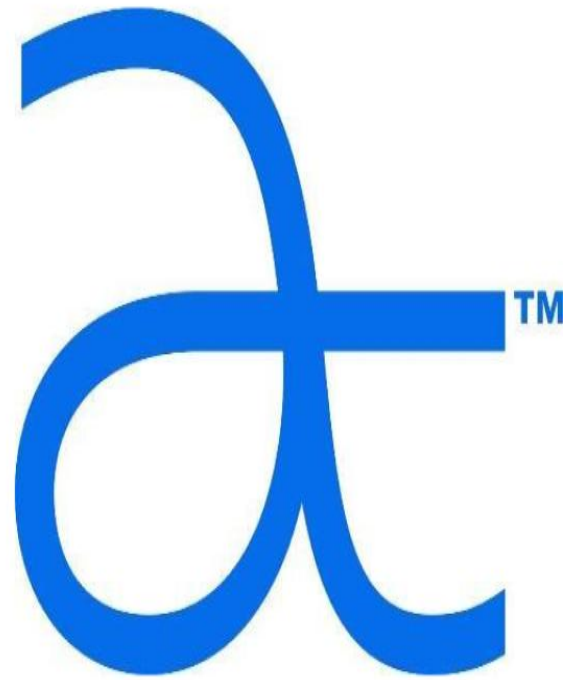
# Axogen Processing Center (APC)

- Fully transferred all Avance processing to APC in December 2023
- Supports BLA requirements for Avance Nerve Graft®
- Provides 3x previous capacity, designed for long-term growth and expansion



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# Product Portfolio



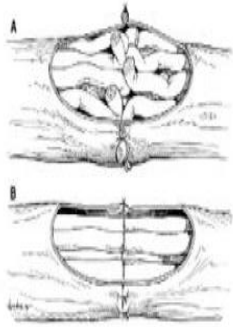
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# Traditional Transection repair options are suboptimal

## SUTURE

Direct suture repair of no-gap injuries

- Common repair method
- May result in tension to the repair leading to ischemia
- Concentrates sutures at the coaptation site



## AUTOGRAFT

Traditional method despite several disadvantages

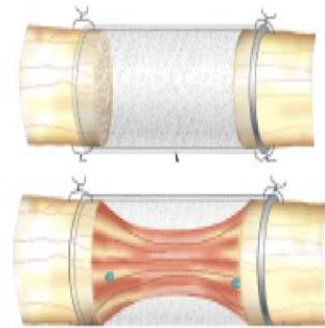
- Secondary surgery
- Loss of function and sensation at harvest site<sup>23</sup>
- High complication rates including wound healing (7%) and chronic pain (23%)<sup>23</sup>
- Limited availability of graft length and diameter



## SYNTHETIC CONDUITS

Convenient off the shelf option; limited efficacy & use

- Provides only gross direction for regrowth
- Limited to small gaps
- 34%-57% failure rate >5mm gaps<sup>24, 25</sup>
- Semi-rigid and opaque material limits use and visualization
- Repair reliant on fibrin clot formation





# Axogen solutions for Transection repair



**α avance<sup>®</sup>**  
nerve graft

Processed human nerve allograft for bridging nerve gaps

Clinically studied off-the-shelf alternative

- A biologically active nerve therapy with more than ten years of comprehensive clinical evidence
- 82-84% meaningful recovery in sensory, mixed and motor nerve gaps in multi-center study<sup>26</sup>
- Eliminates need for an additional surgical site and risks of donor nerve harvest<sup>23</sup>
- Reduces OR time<sup>21</sup>

Structural support for regenerating axons

- Cleansed and decellularized extracellular matrix (ECM)
- Offers the benefits of human peripheral nerve micro-architecture and handling

Revascularizes and remodels into patient's own tissue similar to autologous nerve<sup>27</sup>

16 size options in a variety of lengths (up to 70mm) and diameters (up to 5mm)

These highlights do not include all the information needed to use Avance<sup>®</sup> Nerve Graft safely and effectively. See full instructions for use (IFU) for Avance<sup>®</sup> Nerve Graft



**α axoguard<sup>®</sup>**  
nerve connector<sup>®</sup>

Minimally processed porcine ECM for connector-assisted coaptation

Alternative to direct suture repair

- Reduces the risk of forced fascicular mismatch<sup>28,29</sup>

Alleviates tension at critical zone of regeneration

- Disperses tension across repair site<sup>30</sup>
- Moves suture inflammation away from coaptation face<sup>31</sup>

Remodels into vascularized patient tissue<sup>32-37</sup>

14 size options in lengths of 10mm and 15mm, and diameters up to 7mm

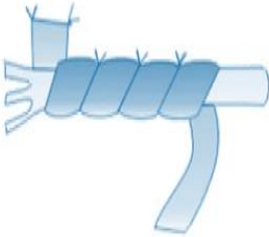
These highlights do not include all the information needed to use Axoguard Nerve Connector<sup>®</sup> safely and effectively. See full instructions for use (IFU) for Axoguard Nerve Connector<sup>®</sup>

# Traditional Compression repair options are suboptimal

## VEIN WRAPPING

Autologous vein

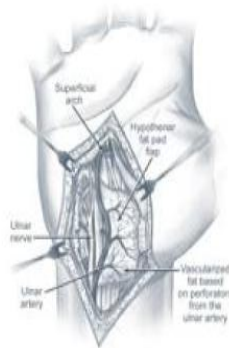
- Barrier to attachment to surrounding tissue
- Requires extra time and skill to perform spiral wrapping technique
- Second surgery site



## HYPOTHENAR FAT PAD

Autologous vascularized flap

- Barrier to attachment to surrounding tissue
- Only wraps part of the nerve circumference
- Increases procedure time



## COLLAGEN WRAPS

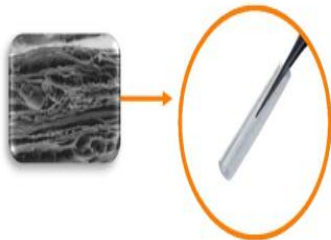
Off-the-shelf

- Semi-rigid material limits use
- Degrades over time and does not provide a lasting barrier to soft tissue attachment



# Axogen solutions for Compression repair

## axoguard nerve protector®



Minimally processed porcine extracellular matrix for wrapping and protecting injured peripheral nerve

Protects repair site from surrounding tissue

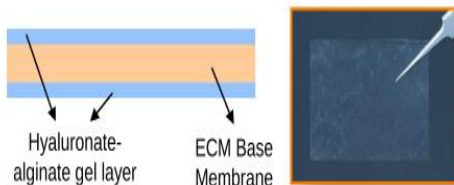
- Processing results in an implant that works with the body's natural healing process<sup>38</sup>
- Minimizes soft tissue attachments<sup>35</sup>

Allows nerve gliding

- Minimizes risk of entrapment<sup>35</sup>
- Creates a barrier between repair and surrounding tissue bed<sup>35</sup>
- ECM revascularizes and remodels into patient's own tissue<sup>32-37</sup>

These highlights do not include all the information needed to use Axoguard Nerve Protector® safely and effectively. See full instructions for use (IFU) for Axoguard Nerve Protector®

## axoguard HA+ nerve protector™



ECM base membrane:

- Processed porcine submucosa extracellular matrix (ECM) base layer
- Vascularizes and remodels to form a new long-term protective tissue layer

Minimally processed porcine extracellular matrix with hyaluronate-alginate gel layer

Lubrication layer:

- Protects nerve in the early critical phase of healing
- Enhances nerve gliding for nerve protection applications where nerve mobility is critical and aids in minimizing soft tissue attachments<sup>32</sup>

Handling characteristics:

- Flat sheet design that easily conforms to tissue
- Coverage of more anatomical locations

Launched August 2023

These highlights do not include all the information needed to use Axoguard HA+ Nerve Protector™ safely and effectively. See full instructions for use (IFU) for Axoguard HA+ Nerve Protector™

# Avive+ Soft Tissue Matrix™



Avive+ Soft Tissue Matrix is a unique, multi-layer amniotic membrane allograft ideal for providing temporary protection for acute injuries.

## Resorbable

Avive+ Soft Tissue Matrix is a temporary resorbable soft tissue barrier for the prevention of soft tissue attachment in an acute wound bed. Made from human birth tissue that will resorb after the critical stage of healing.

## Ease of use

The unique multi-layer design of amnion and chorion provides structural integrity that makes Avive+ easy to handle and, with the epithelial layer facing out on both sides, it can be applied in either direction intra-operatively.

## Inherent properties of amnion

Avive+ leverages the properties of amnion offering a homologous tissue option that has a low immune response and serves as a barrier to separate and reestablish tissue planes.



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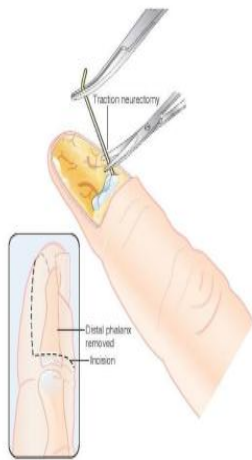
These highlights do not include all the information needed to use the Avive+ Soft Tissue Matrix safely and effectively. See Package Insert (PI) for Avive+ Soft Tissue Matrix

# Traditional Stump Neuroma options are suboptimal

## TRACTION NEURECTOMY

Nerve placed in traction and cut to allow for retraction

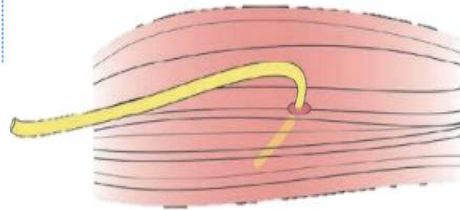
- Simply resecting the nerve results in subsequent neuroma formation and risk of secondary surgery
- Causes traction injury
- High risk of recurrence<sup>39</sup>



## BURYING IN MUSCLE/BONE

Traditional method of neurectomy and neuromyodesis

- Simply resecting the nerve results in subsequent neuroma formation and risk of secondary surgery
- Pain due to muscular contraction or localized pressure
- Larger surgical dissection
- Only 33-40% of patients were satisfied with treatment after burial into bone or muscle<sup>40</sup>



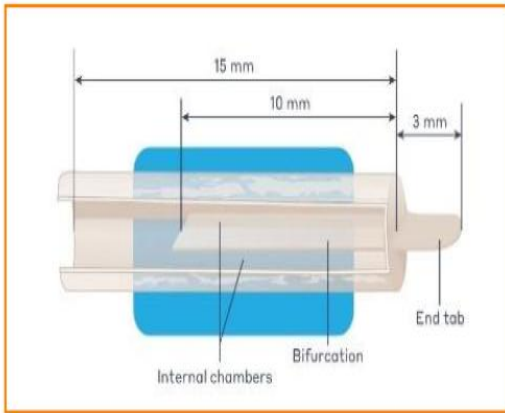
## INJECTIONS

Pharmacologic intervention, typically alcohol or steroids

- Chemical injections are only successful 40% of the time<sup>41,42</sup>
- Temporary solution that has a reduced benefit over time
- May cause considerable side effects



# Axogen solution for Stump Neuroma



Large Diameter Nerve Cap launched in February 2024. 3 larger sizes for larger diameter nerves. Expands addressable procedures in upper and lower extremity.

Proprietary small intestine submucosa (SIS) matrix designed to separate the nerve end from the surrounding environment to protect it from mechanical stimulation and reduce painful neuroma formation\*.

## Protects and isolates

- Reduces the development of symptomatic or painful neuroma formation
- Provides a barrier from neurotrophic factors and mechanical stimulation

SIS Material allows for vascularization and gradual remodeling (as shown in animal studies)<sup>32-37</sup>

- Material gradually incorporates into patient's own tissue, creating a physical barrier to surrounding soft tissue<sup>43</sup>

## Intra-operative versatility

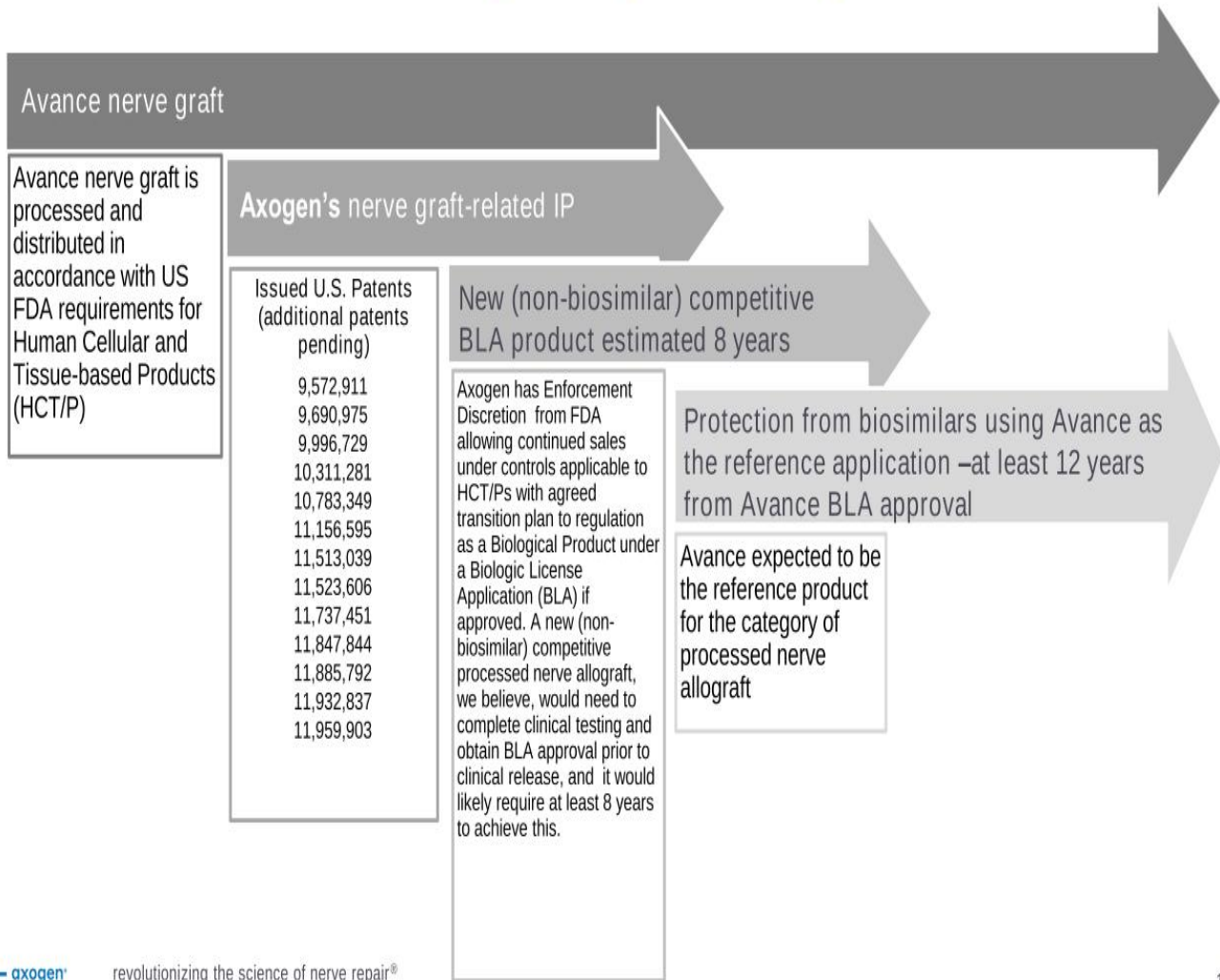
- Ideal for anatomic areas with limited or no musculature
- Alternative to historical techniques such as burying in muscle or bone
- Available in a variety of diameters



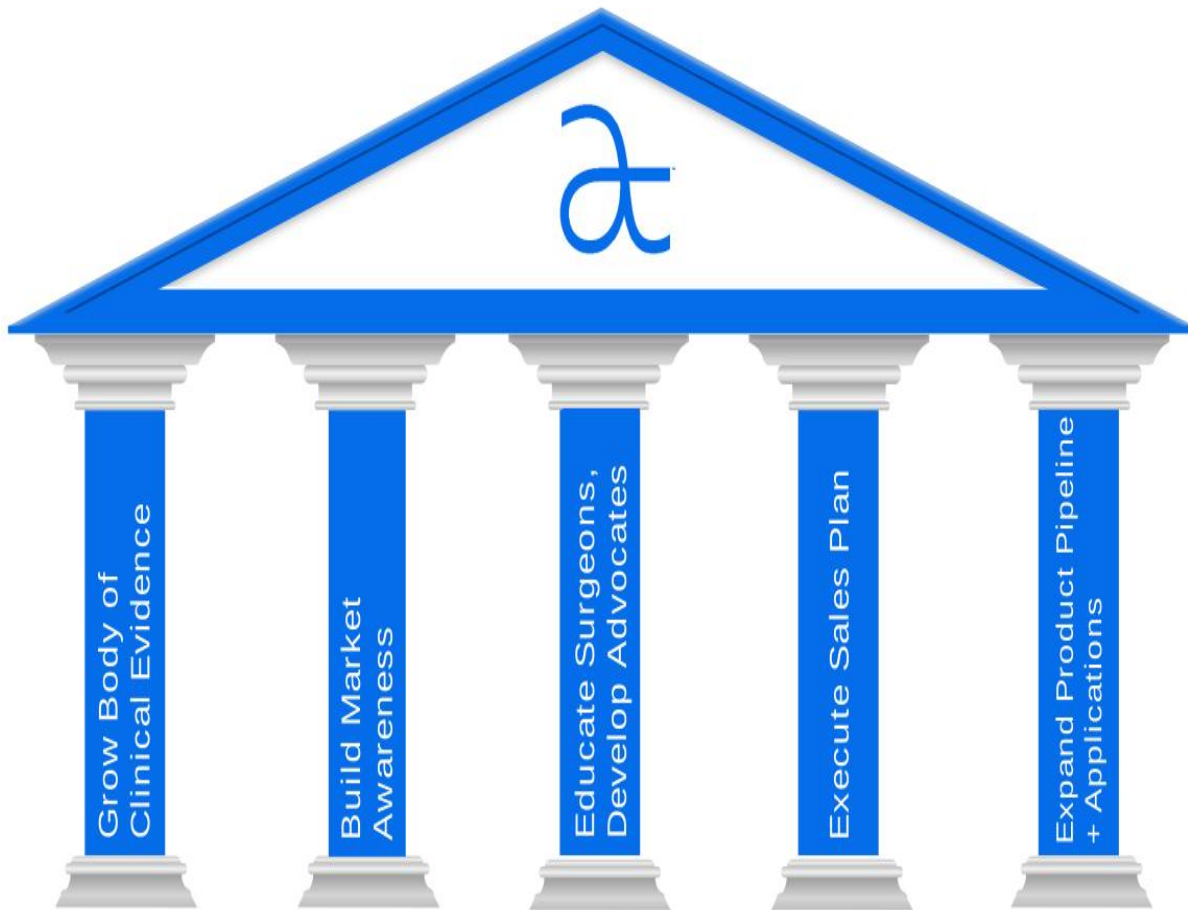
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\*These highlights do not include all the information needed to use Axoguard Nerve Cap® safely and effectively. See full instructions for use (IFU) for Axoguard Nerve Cap® [https://www.axogeninc.com/wp-content/uploads/2019/12/LB-580-R04\\_NerveCapIFU.pdf](https://www.axogeninc.com/wp-content/uploads/2019/12/LB-580-R04_NerveCapIFU.pdf) 18

# Avance Patents and Regulatory Landscape



# Market development strategy





# Strong commitment to developing clinical evidence



## RANGER® Registry Study: Enrollment Complete

- Multi-center clinical study in PNR with >2,700 enrolled to date
- Overall meaningful recovery rates of 82-84%; comparable to autograft

## MATCH® Registry Study: Enrollment Complete

- Avance compared to matched cohort of autograft and synthetic conduits

## Sensation-NOW® Registry Study: Enrollment Ongoing

- Multi-center clinical study in breast neurotization

## REPOSE®: Top line Data Read Out Complete

- Prospective, randomized, controlled study of Axoguard Nerve Cap® vs neurectomy

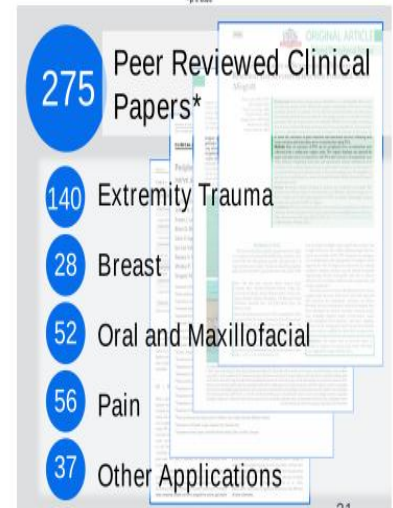
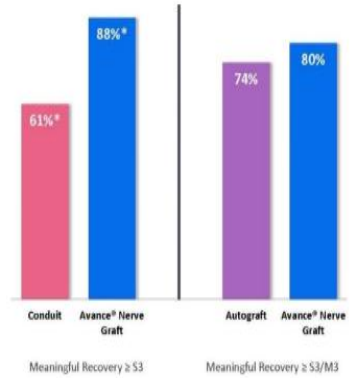
## REPOSE-XL<sup>SM</sup>: Pilot Study Enrollment Ongoing

- Pilot study evaluating the feasibility of large-diameter Axoguard Nerve Cap® for protecting and preserving terminated nerve ends after trauma or amputation

## COVERED<sup>SM</sup>: Enrollment Ongoing

- Prospective, multi-center clinical case series evaluating Axoguard HA+ Nerve Protector™ in first revision cubital tunnel decompression

Outcomes from RANGER Registry <sup>44,45</sup>



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\*Certain publications contain data on multiple applications.

# RECON<sup>SM</sup> : A Multicenter, Prospective, Randomized, Subject & Evaluator Blinded Comparative Study of Nerve Cuffs & Avance Nerve Graft Evaluating Recovery Outcomes for the Repair of Nerve Discontinuities



Safety & efficacy non-inferiority comparison of Avance vs conduit



Evaluated upper extremity digital nerve repair for nerve gaps 5-25mm



220 subjects from up to 25 U.S. centers stratified into gap lengths with two-thirds in the 5-14mm group and one-third in the 15-25mm group

# RECON Study Topline Results

## Primary Endpoint Achieved

- This phase three pivotal study met its primary endpoint for the return of sensory function as measured by static two-point discrimination, and the safety profile was consistent with previously published data
- The data will support the company's Biologics License Application (BLA) with a potential for approval in September 2025.

### Statistical superiority demonstrated at increasing gap lengths

- ✓ Avance demonstrated statistical superiority for return of sensory function (measured by static two-point discrimination) as compared to conduits in gaps greater than 12 mm (p-value 0.021).<sup>19</sup>
- ✓ Avance demonstrated statistical superiority for time to recovery of static two-point discrimination as compared to conduits, returning normal sensation\* up to 3 months earlier in gaps greater than 10 mm (p-value 0.037).<sup>32</sup>

### The safety profile was consistent with previously published data

- ✓ Conduit repairs were observed to have an increased likelihood of persistent and unresolved nerve pain with an incidence of 9 (8%) conduit subjects as compared to 2 (2%) Avance subjects.<sup>32</sup>

\*Normal Sensation is defined by the Medical Research Council Classification (MRCC) score as S4 or return of static two-point discrimination outcomes of  $\leq 6$ mm.



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# REPOSE Study Top Line Results

## Primary Endpoint Achieved

REPOSE met primary endpoint of non-inferiority between the Month 12 pain visual analog scale scores for neurectomy with Axoguard Nerve Cap vs. standard-of-care neurectomy alone (p-value <0.05).

## Statistical superiority demonstrated in Reduction of Total Pain

- ✓ Axoguard Nerve Cap demonstrated statistical superiority vs. standard-of-care neurectomy in the Reduction of Total Pain reported by participants over the full 12-month course of follow-up (p-value <0.05)

REPOSE is a post-market, randomized, comparative clinical study of standard-of-care neurectomy followed by reconstruction of the nerve end with Axoguard Nerve Cap, evaluating recovery outcomes for the treatment of symptomatic neuroma.

### Study Details:

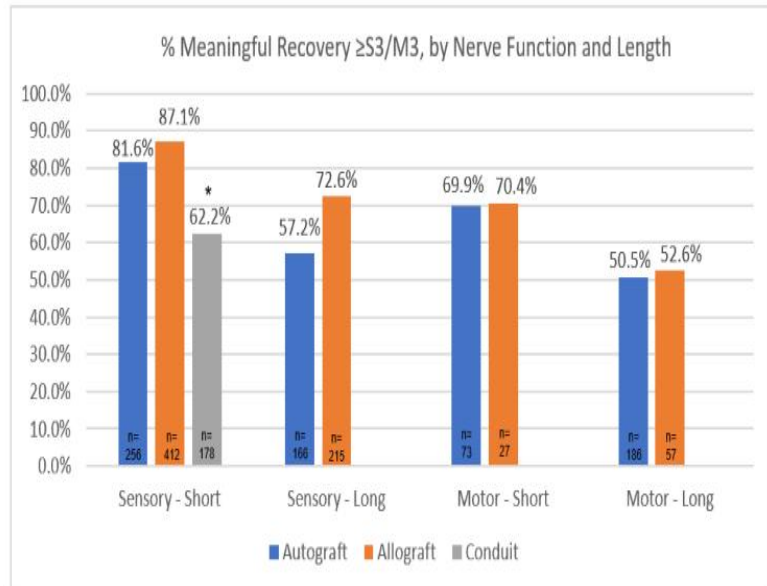
- Multicenter, prospective, randomized, subject blinded trial
- 86 randomized participants
- 12-month follow-up
- Pain, medication, Quality of Life questionnaires, recurrence of neuroma endpoints



## Independent Publication of Nerve Meta-Analysis Provides the Strongest Clinical and Economic Evidence To-Date of the Performance of Avance® Nerve Graft Across All Gap Lengths and Nerve Types

### “Lans et al., A systematic review and meta-analysis of nerve gap repair: Comparative effectiveness of allografts, autografts, and conduits” – Journal of Plastic and Reconstructive Surgery<sup>20</sup>

- Analyzed 35 peer-reviewed studies with 711 allograft, 670 autograft, and 178 conduit repairs, over four decades.
- There were no statistical differences between allograft and autograft outcomes over all gap lengths for both sensory and motor nerve repairs.
- Allograft and autograft repairs delivered significantly better rates of meaningful sensory recovery in short gaps as compared to conduit repairs; 87.1% and 81.6% vs. 62.2%, respectively,  $p < 0.05$ .
- The cost analysis found that allograft does not represent an increased economic burden compared to autograft.



\*statistically significant difference

# Procedure Costs of Peripheral Nerve Graft Reconstruction

Raizman et al.  
PRS Global Open<sup>21</sup>



- Retrospective study of U.S. all-payer data on facility procedure costs from 2018 to 2020. Included over 1,300 nerve repairs.

## Conclusions:

- No significant differences in procedure costs for autograft and allograft repair in either inpatient or outpatient setting.
- OR time was significantly shorter for allograft repairs, in both outpatient and inpatient settings.

## Procedure Costs of Nerve Repair

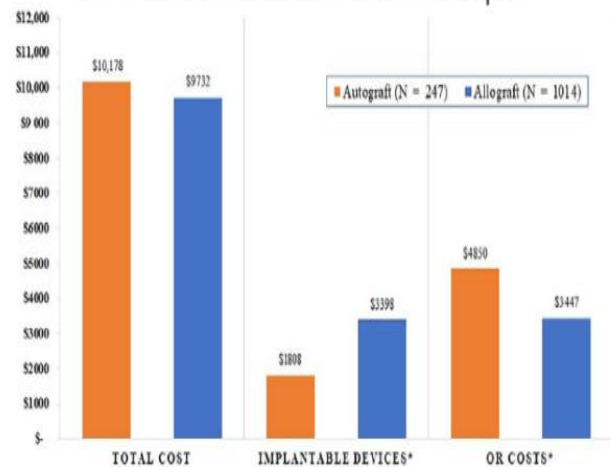


Fig. 2. Outpatient descriptive costs of nerve graft repair type (n = 1261).

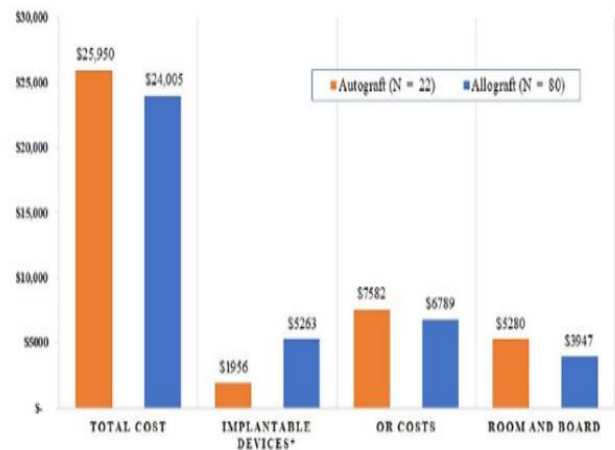


Fig. 3. Inpatient descriptive costs of nerve repair graft type (n = 102).

# Focus on building awareness among clinicians and patients



- Increasing omnichannel engagement with clinicians and patients
- Continuing clinical conference participation both virtually and in-person as appropriate
- Ongoing patient ambassador program
- Garnering positive media attention
- Growing social media presence



.....  
resensation

rethink pain®



revolutionizing the science of nerve repair®

resensation.com

rethink-pain.com

Knowledge is power: continued education and advocacy efforts with patients, clinicians and key legislators elevates the problems associated with numbness.

FOR PATIENTS, SURVIVORS & THEIR CAREGIVERS

BREAST CANCER

# cure 20<sup>TH</sup> anniversary

Cancer Updates, Research & Education\*

SPECIAL ISSUE • 10.2022

## Creating A NEW WAY TO DEFINE BREAST CANCER

THE RECOGNITION OF HER2-LOW STATUS IS RAPIDLY RESHAPING HOW RESEARCHERS AND CARE PROVIDERS THINK ABOUT BREAST CANCER.

**Also in this issue**

**SECONDARY BREAST CANCERS**  
Finding evidence to improve care after completing treatment for primary breast.

**FAST FORWARD**  
Researchers identify the method to predict tumor growth in early treatment decisions.

**POST-MASTECTOMY NUMBNESS**  
A new study suggests that the physical effects of breast cancer treatment can last for years.

### Coping With Sensation Loss After Mastectomy

Chest numbness can be truly daunting, but patients don't have to suffer in silence – and it may not be something they have to live with.

BY CRYSTAL BERRY, MD

**MEET** All kinds of feeling or sight can automatically trigger a patient's anxiety or fear. It can be a relief of feeling, especially in cases where the body is numb.

**SPEAK UP, INVESTIGATE OPTIONS**  
A patient who underwent a mastectomy may be faced with the task of looking for a way to deal with the numbness. Perhaps the best way to deal with the numbness is to speak up and investigate options.

2022 • 8 • Department of Plastic Surgery News

# Breast Reconstruction

A patient's guide to understanding her treatment options

Q&A: Chicago doctor shares her journey and research efforts to reduce racial disparities in care

Breast Reconstruction: Clearing up common misconceptions Page 5

4 things to consider when finding the right plastic surgeon Page 15

## Helping a patient reclaim her time after mastectomy

HELP WOMEN RECLAIM AFTER MASTECTOMY Page 6

# WILDFIRE

Love & Intimacy

APRIL / MAY 2022

Features  
Regaining Feeling and Restoring Intimacy by Jessica de Paz

Oncology **cure** magazine

## NURSINGNEWS

Opinion: Post-Mastectomy Chest Numbness: Oncology Nurses Are Key to Patient Education

November 16, 2022  
Jessica de Paz, BSN, Breast Cancer Survivor

Facebook Twitter LinkedIn YouTube Instagram

Oncology nurses are in a unique position to educate patients with breast cancer about post-mastectomy chest numbness.

OCTOBER 2022 • VOL. 8 • NO. 8

# CONQUER

the patient voice

## Breast Cancer Diagnosis & Patient Advocacy

By Cancer Asked Me What I Was Made of

TO BE CANCER-FREE, I had to be a warrior in my own skin. I learned to fight back in my own way. I learned to be a warrior in my own skin. I learned to be a warrior in my own skin.

BY YOURSELF: DR. MICHELLE BERRY

VERSUS

ANN  
A+ NN  
conquer-magazine.com

TODAY

PINK POWER TODAY

NBC'S KRISTEN DAHLGREN ON HER GROUNDBREAKING PROCEDURE

TODAY 8:43 AM

SIDE-EFFECTS MANAGEMENT BREAST CANCER

### Dealing with Chest Numbness After Mastectomy

By Kristen Casey, PsyD  
October 2022 Vol 8 No 5

Chest numbness is a side effect often ignored or not discussed in breast cancer, but losing physical sensation in nearly 10% of the body can have a profound impact on a woman's physical and emotional life.



# Emphasis on education



- In-person and virtual national education programs
- Customized multimodal learning programs to specific surgeon groups for advanced learning
- Ongoing interactive webinar series covering the principles of nerve repair
- Emphasis on training hand and micro-surgery fellows



masterminds  
of nerve



revolutionizing the science of nerve repair®

# Focused sales execution, increasing market penetration

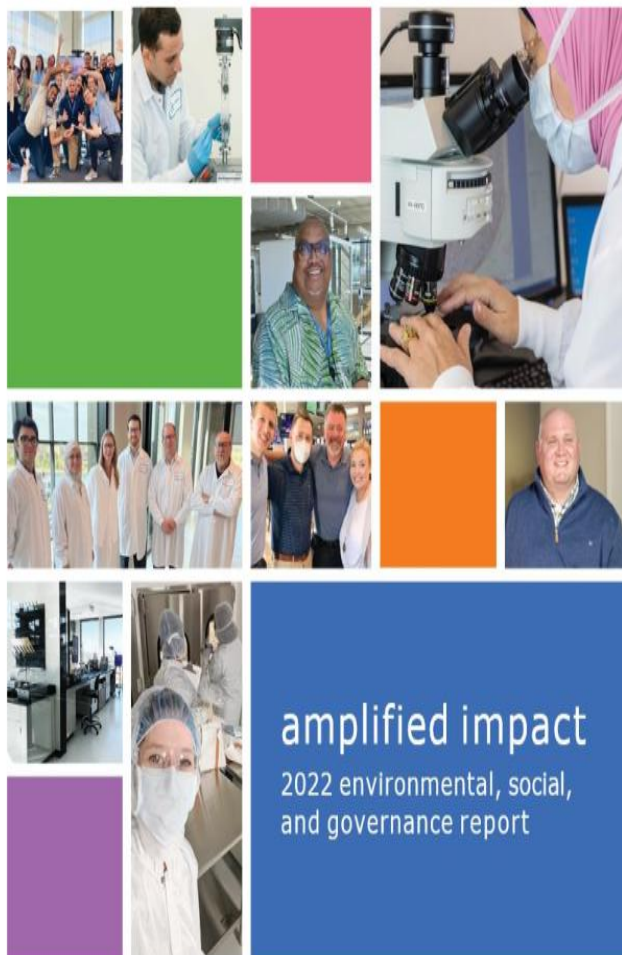


Sales execution focused on driving results

- Continue driving penetration in High-Potential Accounts

Broad sales reach

- U.S. direct sales team
- Supplemented by independent agencies



Committed to our patients, the communities we serve, and our pursuit of advancing the science of nerve repair in ethical and sustainable ways

People Sustainability Business

Diversity, Equity, and Inclusion - Being the Company where exceptional people want to work

Cybersecurity – Data Privacy, Training, and Policies

Compliance – Quality Management System, Regulatory, and Good Manufacturing Practices

Governance – Framework for Ethics Codes and Accountability

Environment – Responsible, Sustainable Operations



revolutionizing the science of nerve repair®



# Executive team



**Michael Dale**  
Chief Executive Officer & Board Director  
Abbot Laboratories  
Effective: 8.9.2024



**Marc Began**  
Executive Vice President, General Counsel  
Abiomed, Boehringer Ingelheim, Novo Nordisk



**Nir Naor**  
Chief Financial Officer  
Arbor Pharmaceuticals, Mölnlycke Healthcare, UCB



**Erick DeVinney**  
Chief Innovation Officer  
Angiotech, PRA Intl



**Jens Schroeder Kemp**  
Chief Marketing Officer  
Ambu, Pera International



**Ivica Ducic, M.D., Ph.D.**  
Chief Medical Officer  
Washington Nerve Institute



**Todd Puckett**  
VP, Operations  
NuVasive, Zimmer



**Stacy Arnold**  
VP, Product Development and Clinical Research  
Artivion (CryoLife)



**Al Jacks**  
VP, Quality Assurance  
VERO Biotech, Alimera Sciences



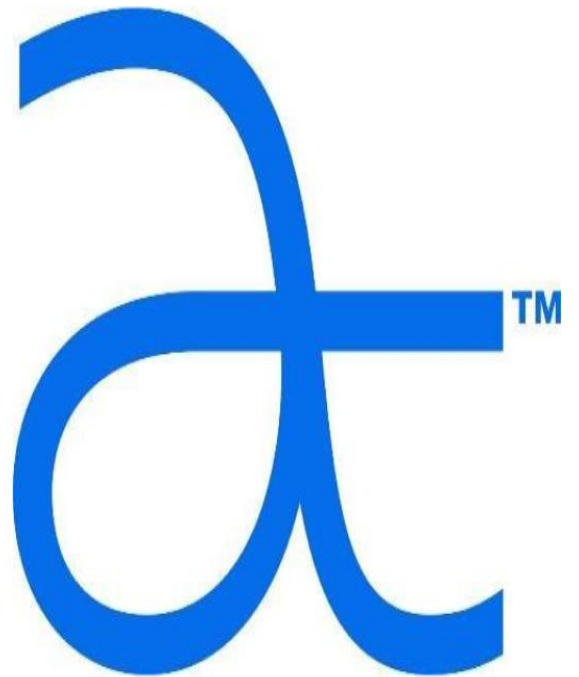
**Doris Quackenbush**  
VP, Sales  
Convatec



revolutionizing the science of nerve repair®

# Appendix

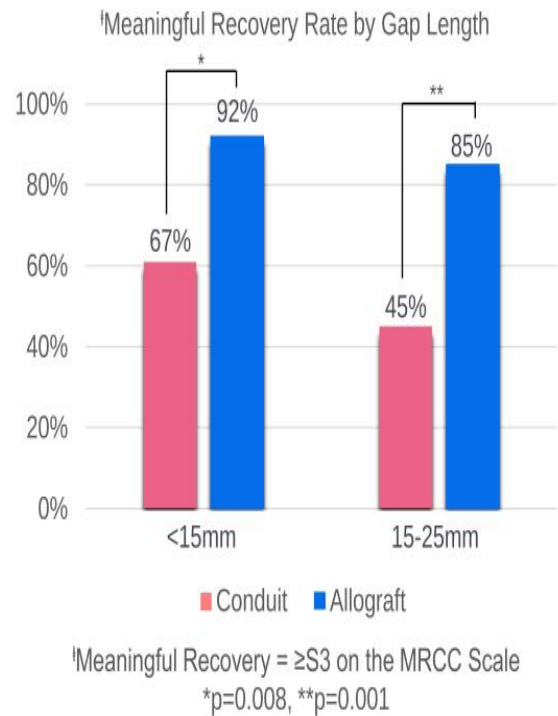
- Key clinical data
- CMS outpatient and ASC reimbursement rates
- Total addressable market
- Cash, debt, and capital structure
- Axogen product portfolio and indications for use



# Avance nerve graft repairs found to be significantly better than conduit repairs

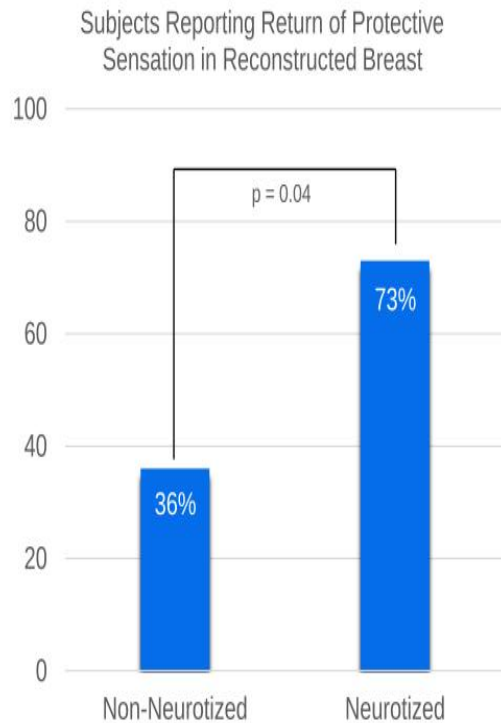
“Leversedge et al., A Multicenter Matched Cohort Study of Processed Nerve Allograft and Conduit in Digital Nerve Reconstruction” – Journal of Hand Surgery, September 2020<sup>44</sup>

- Peer-reviewed publication from the MATCH cohort of the RANGER Registry
- Includes outcomes from 110 subjects with 162 nerve injuries; 113 were repaired with Avance nerve graft and 49 were repaired with manufactured conduit
- Findings show overall meaningful recovery rate was 88% for Avance nerve graft and 61% for conduit (p=0.001) for gaps up to 25mm
- Average static two-point discrimination improved to 9.7mm for Avance nerve graft as compared to 12.2mm for conduit (p=0.018)
  - Note: lower measurement is reflective of improved discrimination and a better outcome
- As gap length increased, Avance nerve graft outcome rates remained consistent while conduit rates declined significantly



# First publication on breast neurotization outcomes with Avance Nerve Graft demonstrated greater return of protective sensation

**“Momeni et al., Flap Neurotization in Breast Reconstruction with Nerve Allografts: 1-year Clinical Outcomes”** – Plastic and Reconstructive Microsurgery Global Open, January 2021<sup>46</sup>

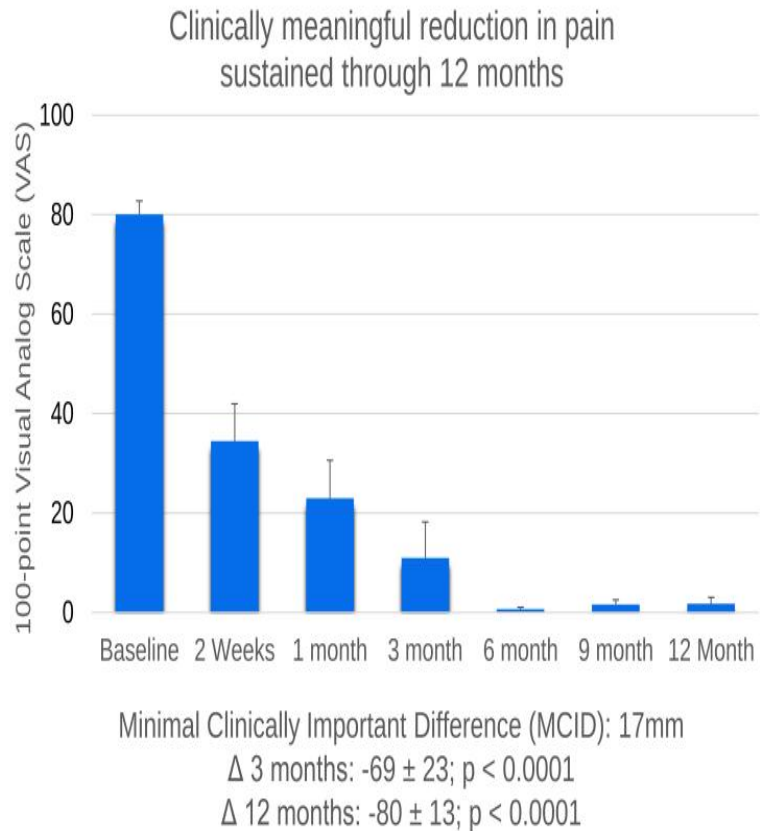


- Early outcomes from a single center study, as part of the Sensation-NOW<sup>®</sup> registry
- 36 breast reconstructions that included:
  - 22 breast reconstructions with Resensation<sup>®</sup>
  - 14 standard non-neurotized breast reconstructions
- Return of Protective Sensation (p=0.04)
  - 73% of the Resensation group
  - 36% of the non-neurotized group
- Neurotization with Avance Nerve Graft resulted in greater return of sensation and return of sensation in more of the breast as compared to standard reconstruction without nerve repair.

# Axogen sponsored REPOSE<sup>SM</sup> pilot study analysis demonstrates clinically significant improvement for subjects with chronic neuropathic pain when using Axoguard Nerve Cap<sup>®</sup> following neurectomy<sup>47</sup>

15-subject, single arm pilot phase evaluating reduction in pain from baseline following surgical excision of the neuroma and placement of the Axoguard Nerve Cap

- Significant & clinically meaningful reduction in pain
- Significant and clinically meaningful improvements in Fatigue, Physical Function, Sleep Disturbance, Pain Interference, Pain Intensity, and Pain Behavior as measured by the validated PROMIS<sup>®</sup> measures
- Positive indicators for reduction in pain medication burden, including opioids
- No recurrence of neuroma





## 2024-25 YOY CMS Proposed outpatient reimbursement rates - hospital and ASC

Although CMS rates<sup>1</sup> only apply to Medicare cases, which represents a small percentage of traumatic injuries, private payors are often influenced by the analysis and decisions made by CMS

CPT Code	Descriptor	C-APC	Hospital Outpatient (HOPD)			Ambulatory Surgery Center (ASC)		
			2024	Proposed 2025	% Change	2024	Proposed 2025	% Change
64912	Nerve allograft repair <sup>2</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$4,579	<b>\$4,644</b>	<b>1.41%</b>
64910	Conduit or vein allograft repair <sup>2</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$4,288	<b>\$4,495</b>	<b>4.82%</b>
64885	Autograft repair (head and neck ≤4cm) <sup>6</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$4,496	<b>\$3,136</b>	<b>-30.25%</b>
64886	Autograft repair (head and neck >4cm) <sup>3</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$3,013	<b>\$3,984</b>	<b>32.23%</b>
64890	Autograft repair (hand and foot ≤4cm) <sup>6</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$4,583	<b>\$3,136</b>	<b>-31.58%</b>
64891	Autograft repair (hand and foot >4cm) <sup>2</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$3,794	<b>\$3,984</b>	<b>5.01%</b>
64892	Autograft repair (arm and leg ≤4cm) <sup>2</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$4,616	<b>\$4,875</b>	<b>5.62%</b>
64893	Autograft repair (arm and leg >4cm) <sup>6</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$4,677	<b>\$3,136</b>	<b>-32.95%</b>
64897	Autograft repair (arm and leg ≤4cm multiple strands) <sup>6</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$4,083	<b>\$3,136</b>	<b>-23.20%</b>
64895-96,98	Autograft repair (all other nerve type) <sup>5</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$3,013	<b>\$3,136</b>	<b>4.08%</b>
64834-36, 40, 56, 57, 62-64	Direct Repair (other hand / foot, arm/leg, repair / transpose, facial, low back,) <sup>5</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$3,013	<b>\$3,136</b>	<b>4.08%</b>
64865	Direct Repair of facial nerve <sup>2</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$3,796	<b>\$3,984</b>	<b>4.95%</b>
64831, 61	Direct Repair (digital, brachial plexus/arm) <sup>4</sup>	5431	\$1,842	<b>\$1,946</b>	<b>5.66%</b>	\$898	<b>\$921</b>	<b>2.52%</b>
64858	Direct Repair (sciatic) <sup>4</sup>	5431	\$1,842	<b>\$1,946</b>	<b>5.66%</b>	\$1,497	<b>\$921</b>	<b>-38.50%</b>

1. National average payment rates. Commercial payments are traditionally 1.5-2x higher than Medicare.
2. Nerve allograft repair CPT 64912, conduit repair CPT 64910, autograft repairs hand/foot >4cm CPT 64891, arm/leg≤4cm CPT 64892, direct repair of facial nerve CPT 64865 remain in C-APC 5432 all continue to meet ASC device intensive criteria
3. Autograft repair head/neck >4cm CPT 64886 meets ASC device intensive criteria in 2025
4. Direct repair digital CPT codes 64831, brachial plexus/arm 64861, and sciatic 64858 remain in C-APC 5431 and do not meet ASC device intensive criteria and in 2025 direct repair sciatic 64858 lost device intensive status.
5. Autograft repair all other nerve type CPT 64895-96,98 and Direct repair other hand/foot CPT 64834-36, leg CPT 64840, repair/transpose CPT 64856, arm/leg CPT 64857, low back CPT 64862-64 remain in C-APC 5432 and do not meet ASC device intensive criteria
6. Autograft repair head/neck >4cm CPT 64885, head/neck >4cm CPT 64890, arm and leg >4cm, and arm and leg ≤4cm multiple strands CPT 64897 remains in C-APC 5432 and no longer meets ASC device intensive criteria in 2025.



Note: Hospital inpatient rates for nerve repair align to DRGs 040, 041, 042 and range from \$11.4k to \$24.5k in the 2025 IPPS Final Rule

## 2024-25 YoY Center for Medicare and Medicaid Services (CMS): Proposed Physician Fee Schedule (PFS)

CPT Codes to f	Descriptor	Physician Fee Schedule (PFS)		
		2024	2025 Proposed	% Change
64912	Nerve allograft repair	\$897	<b>\$880</b>	<b>-1.95%</b>
64910	Conduit or vein allograft repair	\$765	<b>\$752</b>	<b>-1.65%</b>
64885 to 64898*	Autograft repair	\$1,053 to \$1,427	<b>\$1,032 to \$1,400</b>	<b>-1.9% to -2.00%</b>
64831 to 64865*	Direct Repair	\$701 to \$1,548	<b>\$691 to \$1,514</b>	<b>-1.49% to -2.17%</b>

\*excludes add-on procedure codes



## 2019-25 CMS Proposed outpatient reimbursement rates - hospital and ASC

Although CMS rates<sup>1</sup> only apply to Medicare cases, which represents a small percentage of traumatic injuries, private payors are often influenced by the analysis and decisions made by CMS

CPT Code	Descriptor	C-APC	Hospital Outpatient (HOPD)				Ambulatory Surgery Center (ASC)			
			2019	2024	2025 Proposed	6Y % Change	2019	2024	2025 Proposed	6Y % Change
64912	Nerve allograft repair <sup>2</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$1,920	\$4,579	<b>\$4,644</b>	<b>141.88%</b>
64910	Conduit or vein allograft repair <sup>2</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$2,613	\$4,288	<b>\$4,495</b>	<b>72.02%</b>
64885	Autograft repair (head and neck ≤4cm) <sup>6</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$1,920	\$4,496	<b>\$3,136</b>	<b>63.33%</b>
64886	Autograft repair (head and neck >4cm) <sup>3</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$3,127	\$3,013	<b>\$3,984</b>	<b>27.41%</b>
64890	Autograft repair (hand and foot ≤4cm) <sup>6</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$3,075	\$4,583	<b>\$3,136</b>	<b>1.98%</b>
64891	Autograft repair (hand and foot >4cm) <sup>2</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$1,920	\$3,794	<b>\$3,984</b>	<b>107.50%</b>
64892	Autograft repair (arm and leg ≤4cm) <sup>2</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$1,920	\$4,616	<b>\$4,875</b>	<b>153.91%</b>
64893	Autograft repair (arm and leg >4cm) <sup>6</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$1,920	\$4,677	<b>\$3,136</b>	<b>63.33%</b>
64897	Autograft repair (arm and leg ≤4cm multiple strands) <sup>6</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$1,920	\$4,083	<b>\$3,136</b>	<b>63.33%</b>
64895-96,98	Autograft repair (all other nerve type) <sup>5</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$1,920	\$3,013	<b>\$3,136</b>	<b>63.33%</b>
64834-36, 40, 56, 57, 62-64	Direct Repair (other hand / foot, arm/leg, repair / transpose, facial, low back,) <sup>5</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$1,920	\$3,013	<b>\$3,136</b>	<b>63.33%</b>
64865	Direct Repair of facial nerve <sup>2</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$1,920	\$3,796	<b>\$3,984</b>	<b>107.50%</b>
64831, 61	Direct Repair (digital, brachial plexus/arm) <sup>4</sup>	5431	\$4,566	\$1,842	<b>\$1,946</b>	<b>-57.38%</b>	\$1,920	\$898	<b>\$921</b>	<b>-52.03%</b>
64858	Direct Repair (sciatic) <sup>4</sup>	5431	\$4,566	\$1,842	<b>\$1,946</b>	<b>-57.38%</b>	\$1,920	\$1,497	<b>\$921</b>	<b>-52.03%</b>

1. National average payment rates. Commercial payments are traditionally 1.5-2x higher than Medicare.
2. Nerve allograft repair CPT 64912, conduit repair CPT 64910, autograft repairs hand/foot >4cm CPT 64891, arm/leg≤4cm CPT 64892, direct repair of facial nerve CPT 64865 remain in C-APC 5432 all continue to meet ASC device intensive criteria
3. Autograft repair head/neck >4cm CPT 64886 meets ASC device intensive criteria in 2025
4. Direct repair digital CPT codes 64831, brachial plexus/arm 64861, and sciatic 64858 remain in C-APC 5431 and do not meet ASC device intensive criteria and in 2025 direct repair sciatic 64858 lost device intensive status.
5. Autograft repair all other nerve type CPT 64895-96,98 and Direct repair other hand/foot CPT 64834-36, leg CPT 64840, repair/transpose CPT 64856, arm/leg CPT 64857, low back CPT 64862-64 remain in C-APC 5432 and do not meet ASC device intensive criteria
6. Autograft repair head/neck >4cm CPT 64885, head/neck >4cm CPT 64890, arm and leg >4cm, and arm and leg ≤4cm multiple strands CPT 64897 remains in C-APC 5432 and no longer meets ASC device intensive criteria in 2025.



Note: Hospital inpatient rates for nerve repair align to DRGs 040, 041, 042 and range from \$11.4k to \$24.5k in the 2025 IPPS Final Rule

# 2019-25 Center for Medicare and Medicaid Services (CMS): Proposed Physician Fee Schedule (PFS)

CPT Codes <sup>3</sup>	Descriptor	Physician Fee Schedule (PFS)			
		2019	2024	2025 Proposed	6Y % Change
64912	Nerve allograft repair	\$804	\$897	<b>\$880</b>	<b>9.40%</b>
64910	Conduit or vein allograft repair	\$825	\$765	<b>\$752</b>	<b>-8.80%</b>
64885 to 64898*	Autograft repair	\$1,096 to \$1,495	\$1,053 to \$1,427	<b>\$1,032 to \$1,400</b>	<b>-5.84% to -6.36%</b>
64831 to 64861*	Direct Repair	\$713 to \$1,604	\$701 to \$1,548	<b>\$691 to \$1,514</b>	<b>-3.15% to -5.58%</b>

\*excludes add-on procedure codes



# Estimated Trauma total addressable market

Patient Population <sup>(a)</sup>	Source	Adjustments and Rationale
<p><b>136,943,000</b> Annual emergency department visits in the U.S.</p>	2015 National Hospital Ambulatory Medical Care Survey (Table 1) <sup>1</sup>	
<p><b>30,238,000</b> Annual emergency department visits <u>due to injury</u> in the U.S.</p> <p><b>×</b></p> <p><b>4.76%</b> Percentage of emergency department visits with nerve injury</p> <p><b>=</b></p>	2015 National Hospital Ambulatory Medical Care Survey (Table 18) <sup>1</sup>	<ul style="list-style-type: none"> <li>Adjusted from 38,959,000 to exclude 8,721,000 injuries that are unlikely to include a nerve injury (i.e., mental disorders, skin conditions, etc.)</li> </ul>
<p><b>1,440,000</b> Annual emergency department visits with nerve injury in the U.S.</p> <p><b>×</b></p> <p><b>46.2%</b> Percentage of ED nerve injuries estimated to be treated surgically</p> <p><b>=</b></p> <p><b>~665,000</b> Annual ED visits with nerve injury estimated to be treated surgically in the U.S., excluding revisions</p>	<p><i>Noble, et al: J Trauma, Volume 45(1) July 1998.116-122</i><sup>2</sup></p> <p><i>Noble, et al: J Trauma, Volume 45(1) July 1998.116-122</i><sup>2</sup></p>	<ul style="list-style-type: none"> <li>2.8% rate cited in <i>Noble, et al</i> study excluded 113 patients coded with nerve injuries outside of the study scope, but that are in the Axogen scope of nerve repair (brachial plexus and digital nerve injuries). Including these injuries increases the rate to 4.76%.</li> <li>Calculated rate based on various rates in <i>Noble et al</i> study for upper and lower extremity and an estimate for other trauma nerves.</li> </ul>

a) Patient population figures rounded to the nearest thousandth.



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# Trauma total addressable market (continued)

Patient Population <sup>(a)</sup>	Source	Adjustments and Rationale
<div style="border: 1px solid black; padding: 10px; margin-bottom: 10px;"> <p style="text-align: center;"><b>~665,000</b></p> <p style="text-align: center;">Annual emergency department visits with nerve injury that can be treated surgically in the U.S., <u>excluding revisions</u></p> <p style="text-align: center;"><b>×</b></p> <p style="text-align: center;"><b>7.4%</b></p> <p style="text-align: center;">Revision cases</p> </div> <p style="text-align: center;"><b>=</b></p> <p style="text-align: center;"><b>714,000</b></p> <p style="text-align: center;">Annual emergency department visits with nerve injury that can be treated surgically in the U.S., <u>including revisions</u></p> <p style="text-align: center;"><b>↓</b></p> <p style="text-align: center;"><b>~700,000</b></p> <p style="text-align: center;">Company estimate of trauma total addressable market</p>	<p>See calculation on previous slide</p> <p><i>Portincasa et al: Microsurgery</i> 27:455-462, 2007<sup>4</sup></p>	<ul style="list-style-type: none"> <li><i>Portincasa et al</i> suggests that a revision procedure was necessary in 7.4% of the patients within 6 months of the initial surgery.</li> </ul>

a) Patient population figures rounded to the nearest thousandth.

# Estimated \$2.7B value of market opportunity in existing applications

	Projected Incidence <sup>(a)</sup>	×	Weighted Average Procedure Value	=	Estimated Total Addressable Market
Trauma	700,000 100%		\$2,715		\$1,900M 100%
Trasection injuries >5mm (b)	203,000 29%		\$5,515		\$1,120M 59%
Trasection injuries <5mm	198,000 29%		\$1,200		\$238M 12%
Non-Transected Injuries (c)	293,000 42%		\$1,825		\$535M 28%
Carpal and Cubital Tunnel Protection	130,000		\$2,100		\$270M
Oral and Maxillo-Facial (OMF)	56,000		\$5,400		\$300M
Breast Reconstruction Neurotization	24,500 flaps (15,000 patients)		\$10,200		\$250M
Totals	>900,000 (potential)				>\$2.7B

a) Estimated Annual incidence of PNI surgery are figures rounded to the nearest thousandth except for Breast Reconstruction Neurotization (rounded to nearest hundredth).

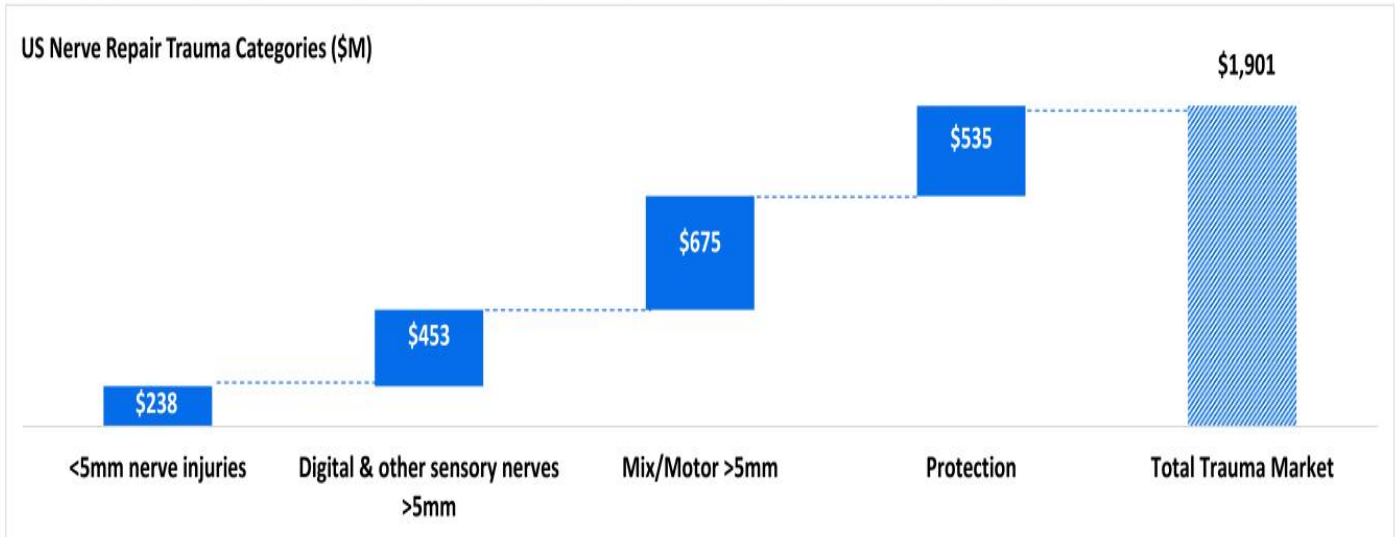
b) Trasection injuries > 5mm assumes a factor of 1.22 nerve repairs per procedures, and utilization of the Axogen portfolio of products, based upon data observed in the RANGER® registry.

c) Protection includes non-transected compression and crush injuries including protection from surrounding soft tissue attachments.



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We continue to see a significant growth opportunity in the trauma market as we leverage new clinical & health economic data and product launches, by category



Category	Algorithm	Trends and Growth Levers
<ul style="list-style-type: none"> <li>Short gap transected nerve injuries</li> </ul>	Low	<ul style="list-style-type: none"> <li>Routine trauma moving to ASCs and lower cost sites of care</li> <li>Education and awareness of proper nerve repair technique</li> <li>Improve procedure awareness and scheduling across all care settings</li> <li>Private payer adoption of improved CMS reimbursement guidelines</li> </ul>
<ul style="list-style-type: none"> <li>Digital Sensory 5-25mm</li> <li>Digital Sensory &gt;25mm</li> </ul>	Low	<ul style="list-style-type: none"> <li>Routine trauma moving to ASCs and lower cost settings</li> <li>Education and awareness of proper nerve repair technique</li> <li>New Clinical data from Recon/Meta-analysis</li> <li>All Payor Procedural Cost analysis</li> <li>Societal support for standard of care</li> <li>Improved private payer reimbursement</li> <li>Activating middle adopters</li> </ul>
<ul style="list-style-type: none"> <li>Mixed/Motor 5-25mm</li> <li>Mixed/Motor &gt;25mm</li> </ul>	Low	<ul style="list-style-type: none"> <li>Motor clinical outcome data from Meta-analysis</li> <li>Societal support for standard of care</li> <li>Prof ed on appropriate surgical technique &amp; algorithm</li> <li>Improved private payer reimbursement</li> <li>Activating middle adopters</li> </ul>
<ul style="list-style-type: none"> <li>Protection from non transected nerve injuries</li> </ul>	Low	<ul style="list-style-type: none"> <li>New product launches of Axoguard HA+™ and Avive+ Soft Tissue Matrix to address acute and chronic applications</li> <li>Increased awareness of Non-Transected Nerve Injuries</li> <li>Clinical evidence generation</li> <li>Professional education on appropriate surgical technique &amp; algorithm</li> <li>Reimbursement coding and coverage</li> </ul>

Axogen has, until now, focused primarily in digital and short gap but new evidence and product launches will open full peripheral nerve injury trauma market





# Balance sheet and capital structure

Balance Sheet Highlights	September 30, 2024
Cash	\$30.5 million*
Total Long-term Debt	\$47.3 million**

Capital Structure (shares)	September 30, 2024
Common Stock	44,002,323
Common Stock Options, RSUs, PSUs	9,436,475
Common Stock and Common Stock Equivalents	53,438,798

\* Includes Cash, Cash Equivalents, Restricted Cash, and Investments

\*\* Total long-term debt includes debt proceeds under the terms of the agreement with Oberland Capital does not include unamortized debt discount and deferred financing fees.

# Axogen comprehensive portfolio of products

## Avance® Nerve Graft

- Regulatory Classification: Avance Nerve Graft is processed and distributed in accordance with US Food and Drug (FDA) requirements for Human Cellular and Tissue-based Products (HCT/P) under 21 CFR Part 1271 regulations, US State regulations, and applicable international regulations. Axogen Corporation is accredited by the American Association of Tissue Banks (AATB). Additionally, international regulations are followed as appropriate.
- Indication for Use: Avance Nerve Graft is processed nerve allograft (human) intended for the surgical repair of peripheral nerve discontinuities to support regeneration across the defect.
- Contraindications: Avance Nerve Graft is contraindicated for use in any patient in whom soft tissue implants are contraindicated. This includes any pathology that would limit the blood supply and compromise healing or evidence of a current infection.

## Axoguard Nerve Connector®

- Regulatory Classifications: Class II Medical Devices - 510(k) cleared, Class III Medical Devices, CE Marked (EU), Class 4 (CA)
- Indications for Use (US): The Axoguard Nerve Connector is indicated for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity. The Axoguard Nerve Connector is supplied sterile and is intended for single use.
- This product is intended for use by trained medical professionals.
- Indications for Use (EU and UK): The Axoguard Nerve Connector is indicated for the repair of peripheral nerve discontinuities with gaps up to 5 mm. The Axoguard Nerve Connector is supplied sterile and is intended for single use.
- This product is intended for use by trained medical professionals.
- Contraindications: This device is derived from a porcine source and should not be used for patients with known sensitivity to porcine material. This device is not intended for use in vascular applications.

## Axoguard Nerve Protector®

- Regulatory Classifications: Class II Medical Devices - 510(k) cleared, Class III Medical Device, CE Marked (EU), Class 4 (CA)
- Indication for Use: Axoguard Nerve Protector is indicated for the repair of peripheral nerve injuries in which there is no gap. The Axoguard Nerve Connector is supplied sterile and is intended for single use.
- This product is intended for use by trained medical professionals.
- Contraindications: This device is derived from a porcine source and should not be used for patients with known sensitivity to porcine material. This device is not intended for use in vascular applications.



# Axogen comprehensive portfolio of products (Cont'd)

## Axoguard Nerve Cap®

- Regulatory Classification: Class II Medical Device – 510(k) cleared
  - Indications for Use: Axoguard Nerve Cap is indicated to protect a peripheral nerve end and to separate the nerve from the surrounding environment to reduce the development of symptomatic or painful neuroma.
  - This product is intended for use by trained medical professionals.
  - Contraindications: Axoguard Nerve Cap is derived from a porcine source and should not be used for patients with known sensitivity to porcine derived materials. Axoguard Nerve Cap is contraindicated for use in any patient for whom soft tissue implants are contraindicated; this includes any pathology that would limit the blood supply and compromise healing, or evidence of a current infection. Axoguard Nerve Cap should not be implanted directly under the skin. This device is not intended for use in vascular applications.
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- **Axoguard HA+ Nerve Protector™**
    - Regulatory Classifications: Class II Medical Devices - 510(k) cleared (K223640)
    - Indication for Use: Axoguard HA+ Nerve Protector is indicated for the management of peripheral nerve injuries where there is no gap.
    - This product is intended for use by trained medical professionals.
    - Contraindications: Axoguard HA+ Nerve Protector base membrane is derived from a porcine source and the lubricant coating is composed of sodium hyaluronate and sodium alginate. The Axoguard HA+ Nerve Protector should not be used for patients with known sensitivity to porcine, alginate, or hyaluronate materials. This device is not intended for use in vascular applications.
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- **Axoguard HA+ Nerve Protector™**
    - Regulatory Classifications: Class II Medical Devices - 510(k) cleared ( K231708)
    - Indication for Use: Axoguard HA+ Nerve Protector is indicated for the management of peripheral nerve injuries where there is no gap, or following closure of the gap.
    - This product is intended for use by trained medical professionals.
    - Contraindications: Axoguard HA+ Nerve Protector base membrane is derived from a porcine source and the lubricant coating is composed of sodium hyaluronate and sodium alginate. The Axoguard HA+ Nerve Protector should not be used for patients with known sensitivity to porcine, alginate, or hyaluronate materials. This device is not intended for use in vascular applications.

## Axogen comprehensive portfolio of products (Cont'd)

### Avive+ Soft Tissue Matrix™

- Regulatory Classification: Avive+ Soft Tissue Matrix is processed and distributed in accordance with US Food and Drug (FDA) requirements for Human Cellular and Tissue-based Products (HCT/P) under 21 CFR Part 1271 regulations, and US State regulations. Axogen Corporation is accredited by the American Association of Tissue Banks (AATB).
- Intended Use: Avive+ Soft Tissue Matrix is processed amniotic membrane intended for use as a soft tissue barrier.
- This product is intended for use by trained medical professionals.
- Contraindications: Avive+ Soft Tissue Matrix is contraindicated for use in any patient in whom soft tissue implants are contraindicated. This includes any pathology that would limit the blood supply and compromise healing or evidence of a current infection.



# Footnotes

1. National Hospital Ambulatory Medical Care Survey: 2015 Emergency Department Summary Tables – Table 18. [https://www.cdc.gov/nchs/data/nhamcs/web\\_tables/2015\\_ed\\_web\\_tables.pdf](https://www.cdc.gov/nchs/data/nhamcs/web_tables/2015_ed_web_tables.pdf)
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# Footnotes

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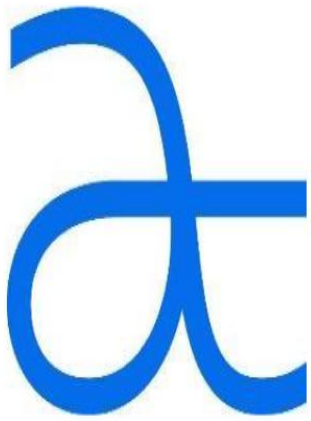
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